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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 5/00, 5/32, 11/00 — A1

(11) International Publication Number: WO 97/47338

(43) International Publication Date: 18 December 1997 (18.12.97)

(21) International Application Number: PCT/US96/17534

(22) International Filing Date: 4 November 1996 (04.11.96)

(30) Priority Data:
08/661,903 12 June 1996 (12.06.96) US

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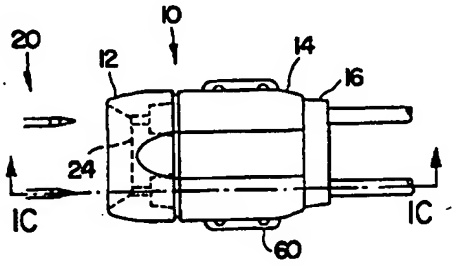
(81) Designated States: AU, BR, CN, CZ, JP, KP, KR, MX, RU, SG, SK, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: DEVICE FOR SUBCUTANEOUS ACCESSIBILITY



(57) Abstract

An implantable device (10) for use in hemodialysis, plasmapheresis, and other fluid exchange therapy treatments comprising a needle guidance element (12), a catheter locking element (16), and a protective cowling (14) accommodating the internal elements.

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DEVICE FOR SUBCUTANEOUS ACCESSIBILITY

FIELD OF THE INVENTION

The present invention relates generally to apparatus that allows access to the vascular system of a human (or other animal), particularly for the high-volume fluid flow required in hemodialysis, plasmapheresis, and other fluid exchange therapies. More particularly, the present invention relates to a septum-less subcutaneously implantable access of single or dual-lumen construct and a mating needle apparatus.

BACKGROUND OF THE INVENTION

There exists a class of devices for accessing fluid spaces and vessels within a human (or animal) body that are generally referred to as "ports". Herein, "vessel" is defined as any conduit carrying a fluid within the patient's body. These prior art devices comprise a chamber having an access opening sealed by means of a septum and having an egress from a second location leading to a catheter disposed within a fluid space or vessel. The septum allows a needle to pass into the chamber, but then closes when the needle is removed, thereby preventing fluid leakage from within a space or vessel and also anything from entering or exiting the chamber. These devices are usually implantable below

the skin to prevent infection, other contamination, and mishandling.

Ports are designed for relatively infrequent use, perhaps once a week, and, importantly, for flow rates of 50 milliliters per minute or less, as is common during chemotherapeutic treatment. Modification of these devices for hemodialysis, plasmapheresis, and other fluid exchange therapies, which require much greater flow rates, by simply enlarging the device components, poses several serious drawbacks that effectively limit use in such applications. First, the septum degrades quickly due to the larger gauge needles necessary to accommodate the flow rates required in hemodialysis. Repeated puncturing of the septum by these large needles produces numerous free-floating septum fragments that can find their way into the circulatory system. Accordingly, the useful life of the devices is substantially shortened, thereby defeating one of the purposes of using an implantable subcutaneous device. Second, the flow path has several stagnation points where clots may form and also is not completely flushable or easily cleaned, thereby providing breeding grounds for infection, once contaminated or a build-up of material which may adversely affect function. Third, the flow path is not streamlined and contains flow path obstructions, sharp corners, and abrupt changes in flow area and flow direction. This tends to increase the shear stress and turbulences experienced by blood flowing through the device due to the significantly higher flow rates required in hemodialysis, thereby increasing erythrocyte damage and platelet activation. Also, the tortuous flow path increases the flow path resistance and the pressure drop through the devices,

such effects can increase air release and foaming, causing the dialysis machine's safety alarms to activate. A general limitation in all relevant prior art devices is the lack of a streamlined flow path. Without such streamlining, stagnant volumes exist where clots may form and shear stress is higher, tending towards erythrocytic damage. Such locations cannot be flushed or easily cleaned. Blood residue remaining in the devices after flushing may clot and provide breeding grounds for infection, once contaminated. In addition, pressure drops and abrupt flow direction changes may damage blood components.

The present invention is also useful for other liquid or fluid (including gases) transfer purposes into and out of human and animal bodies, including the transfer of externally prepared solutions for cleaning, flushing, dialysis, chemical agent delivery, transfusions, blood donation, insufflation, wound drainage, etc.

Accordingly, it is a principal object of this invention to overcome the above illustrated inadequacies and problems of extant devices by providing a totally implantable access means suitable for repeated use in applications (*e.g.*, hemodialysis with blood flow rates of 250 milliliters per minute or more yet with low pressure drops along the flow path).

It is another principal object of the invention to optimize fluid flow in hemodialysis particularly and in other applications referred to generally, above.

It is another object of this invention to provide a substantially laminar flowstream

It is yet another object of this invention to minimize flow discontinuities and to substantially match the internal diameters of the injecting cannula and the

receiving catheter, and a related object is to bring the exit end of the cannula and the entrance end of the catheter into close proximity..

It is a further object to provide means where the flow path is streamlined and provides substantially no stagnation points, no flow discontinuities, and also to provide an apparatus where the entire flowstream is flushable.

It is a further object to the invention to minimize internal fluid collection zones or stagnant volumes in such a device.

It is a still further object to have lower clotting, stenosis, and infection rates than synthetic grafts.

It is yet another object to have lower infection and lumen clotting than percutaneous catheters.

It is a still further object of this invention to provide apparatus suitable for single and dual-lumen catheter systems.

It is yet another object of this invention to provide an access device that is less painful during needle insertion and more accommodating during dialysis for the patient.

It is a further object of the invention to minimize irritation and other adverse effects associated with intermittent skin puncture over a course of days, months or years of repetitive access.

It is a further object to secure the needle within the access device during the dialysis session.

It is a further object of the invention to enhance the devices to more effectively lock in a cannula to the device to avoid inadvertent separation, yet allow ease of deliberate release of the cannula.

It is another object of the invention, when using dual-lumen catheters, to secure both needles to each other.
It is a further object of the invention to provide ease of manufacture and assembly of such device consistent with enhanced locking.
A further object of the invention is to establish economy of the lock devices for disposability.
It is a further object of the invention to provide enhanced cannula and obturator handling external to a patient via hub devices coordinated with the structure and functions of the locking devices.
It is also an object of the invention to accommodate multiples of the foregoing objects together.

SUMMARY OF THE INVENTION

The foregoing objects are met by a single subcutaneously implantable device for accessing a vessel within a patient's body, or a ganged pair of such devices or separate such devices, each device including (a) an access guidance means having an entrance and passageway for receiving a cannula and accommodating a locking means for the cannula, (b) flexible locking means, (c) needle guidance means of sufficient hardness to prevent scoring or chipping, (d) valve means for allowing access to a vessel when a cannula is inserted into the device and preventing fluid flow through the device when the cannula is withdrawn, the valve means having a closable passageway that accepts an inserted cannula and comprising an access portion, a sealing portion, and a distal portion; (e) a catheter attachment having a closable passageway with seating means

disposed therein, and (f) a shell capable of enclosing these elements.

A resilient elastomeric means for producing a contact sealing pressure is arranged around the sealing portion of the valve means. This resilient means includes, in a preferred embodiment, a cylindrical band made of an elastomeric material that provides forces on the sealing portion and is located outside the fluid path. The sealing portion ordinarily prohibits fluids from passing the seal. But when a mechanical device is inserted percutaneously, and guided to the valve's access portion by the access guidance means, the mechanical device engages the needle guidance means disposed within the access portion of the valve with sufficient axial force to overcome the radial force exerted on the sealing portion by the resilient means for sealing. It is important to note that the needle assembly forces the guidance means and the guidance means pushes the sealing portion open. The needle assembly, actually the obturator in a preferred embodiment, then enters the opened sealing means without the point puncturing or cutting the sealing means. The needle guidance means itself opens the slit to allow the needle assembly to enter and then to slip through the sealing means. So in this fashion the needle assembly passes through the valve until it engages the catheter attachment seating means. This operation provides access through the valve to the valve's distal portion and, ultimately, the vessel lumen, as the distal portion of the catheter that is attached to the access device via the catheter attachment, extends into a vessel lumen. An advantage of the present invention is found by minimizing the spacing between the end of the cannula and the beginning

of the catheter, and by smoothly fairing the internal surfaces of the short connecting or transition passageway to the interior surfaces of the cannula and the catheter. If there are disparate internal diameters the short connecting transition passageway smoothly and uniformly accommodates the internal diameters. This arrangement provides a flow path with minimum flow discontinuities and a path that is easily flushed.

The catheter maybe flexibly attached to the surrounding tissue supporting the catheter, but the flexibility allows the device's position to move relative to the surrounding tissue. A strain relief assembly may also be provided at the catheter attaching end of the device to relieve the tension on the catheter attachment to the device to prevent the catheters from kinking. Edges of the strain relief structure can be sutured or stapled to tissues and the strain relief wrap can in turn hold other portions of the device.

The access device may be flexibly anchored to the surrounding tissue. In a preferred embodiment this anchor means is attached to the device to allow the cannula entrance of the device to be rotated, preferably as much as 50 degrees relative to the anchor means in at least two directions. This, together with the normal movement of the skin allows the needle assembly to enter the skin at a location on the skin that is healed, or at least a skin location that has had ample time to heal. This ability to access larger areas of skin for inserting the needle assembly is a significant advantage over relatively fixed ports.

The resilient means for sealing is arranged and constructed to close the valve's potential lumen such that the longitudinal transition profile of the valve's

access portion forms a particular shape. The shape of the access portion allows for the generally conical point of the needle obturator to open or push apart the access portion and the slit in the sealing portion with wedging action as the point is pushed through the seal. The axial point pushing force overcomes the radial biasing force exerted by the resilient means for sealing and the internal stresses of the sealing portion as the point enters the sealing portion without cutting the valve material. Because no cutting occurs, no particles of valve material are generated, as is common with septums in ports now in use. Furthermore, the number of penetration cycles to failure in the present invention is significantly higher than with septum ports, as negligible damage occurs during needle penetration.

The flow path transitions between the cannula lumen, the short connecting passage in the access device, and a catheter lumen are arranged and constructed to provide for maximum smoothness and continuous flow paths without abrupt changes in flow diameter and only gentle changes in flow direction. All narrowing and broadening of the flow path is gradual, with angles of preferably 25 degrees or less.

The invention also provides for a hollow needle apparatus or cannula with an outside diameter that matingly corresponds to the entry passageway of the access device, and an obturator that is inserted into the needle lumen filling the lumen and which has a tip portion that extends beyond the cannula. This needle/obturator combination provides a needle assembly with a pointed end, and an outer surface having smooth transitions, which are formed to puncture tissue easily and to open the valve without damaging it. The

hollow needle is preferably metal so that the n edle wall is as thin as possible considering the stresses on the needle. This is important since the larger the internal diameter of the needle the lower is the flow resistance. The lowest flow resistance consistent with the physical constraints and needs of the patient and the function being performed, especially in the high flow rate hemodialysis field, is an important goal of the present invention and a major advantage of the present invention.

The flexible lock preferably comprises a resilient plug (preferably made of a medical quality elastomer) surrounding an inserted hollow metal cannula, but containing rigid internal blades or strips (preferably made of super hard material such as a hard ceramic or hardened metal, e.g. titanium nitride) that extend radially in locking use and are configured and arranged to inscribe the outer cannula surface and bear on it with a high reaction force. When an inadvertent axial pull on the needle from outside (or the push of a muscular contraction from within) places an expelling force on the needle, the beginning of movement increases the locking effect. The blades or strips have inner edges that form one or more teeth of pointed or blunt ends, such teeth having shallow clearance angles with respect to the passage axis. The blades have outer edges that are locked in geometrically by a tapered inner surface of the shell.

Deliberate removal can be done by rotating and/or wiggling (spiral or combination of axial/rotation movements) of the cannula so that the orientation of the blades shifts from essentially radial to essentially chordal or non-radial alignment relative to the device's

int rnal passage axis. When the plug and blades are disposed non-radially the cannula can be withdrawn easily. The rotation or the like is then relaxed (after complete removal of the cannula) and the blades are restored to radial alignment by the elasticity of the plug.

When the needle is reinserted (typically one or more days later) the entering cannula passes through the inner edges of the blades. Generally there is a full withdrawal of a cannula or a full insertion; but partial insertion and/or withdrawals can also be accommodated.

The resilient plug body is set radially apart from the cannula surface to avoid shedding or uneven friction due to thermal conditions or other sources of expansion/contraction of the flexible plug (*e.g.*, made of silicone rubber). The flexible plug material is preferably cast in a mold about the aligned (radial) blades. Holes or the equivalent are provided in the blades so that the flexible material on both sides of each blade is bridged via such holes or other means and the blades are securely aligned therein radially and with inner and outer edges of the blades extending beyond inner and outer plug surfaces. Generally, there is a low axial direction friction meeting of the blade outer edges and the tapered (frusto-conical) shell inner surface. A ceramic shell with a smooth finish inner tapered surface meets this criterion very well. Similarly the blade inner edges slide along the cannula outer surfaces with low friction. The hardness of all such surfaces and the rigidity and dimensional stability of blades, cannula and shell are related to the above features and also important *per se*.

The valve, in a preferred embodiment, may include a plug of sealing material with a slit cut in the center and with a spring loading means holding the slit closed to block the internal passage of the device when the cannula is withdrawn and yet is readily opened as the needle assembly (obturator) is inserted without damage as described above. Similar valves can be used with more than one slit opening and closing as described above. In any such design, it is preferable to have automatic spring loaded closing when the cannula is withdrawn and easy opening as a needle assembly or the like is inserted through the device's internal passage to maintain contact sealing stress when closed. The present invention causers no cutting due to the manner of opening the seal described above.

Ease of use and product reliability are also accommodated by features discussed below.

The invention also includes an extracorporeal needle assembly hub structure or pair of such structures usable in combination with the implantable subcutaneous access device(s) for straight cannula alignment and aligned cutter and stiffener (a separate element or integrated with the cannula) that has to penetrate the skin, find the entrance to the inner passage of the subcutaneous device and pass through it to a lock-in site therein without coring the skin. The hub has a Y-connection of three internal paths: (a) external fluid passage, (b) passage to the cannula and (c) a cannula/cutter access leg, all cooperating with shallow bend angles and gradual curvatures at the Y-intersection in the fluid path and straight line access to the needle assembly locking device, as consistent with practical and economic mass production while achieving

a benign flow path which does not damage cellular blood components and meets previously stated criteria for the blood path..

The needle is initially inserted through the hub structure (or comes preassembled with it) and has an internal obturator with a point that passes out of the needle distal end for penetrating skin and subcutaneous tissue and serving as an aid to finding the subcutaneous entrance to the access and lock device. The obturator point is faceted so that its cutting is done along meeting line edges of the facets. However, when the obturator point has cutting edges that extend from the center towards the outer surface of the obturator. but as cutting edges extend to the outer surface of the obturator the edges are softened or dulled so that the obturator does not cut, score, or otherwise mar the internal wall of the passage or interiors of the locking and sealing components of the access device which form part of the passage. The obturator edges are softened in a preferred embodiment by facets but in a larger number of facets, set at shallower angles, than the facets at the point. In yet another preferred embodiment the facets are concave rather than flat, where the intersection of the facets provides a sharper edge. The section of the obturator with the dulled edges blends into a beveled end of the cannula. Once the needle assembly is fully inserted, locked and sealed in place, the obturator can be withdrawn to leave a smooth flow path beginning in the needle hub structure and continuing therein to a smooth blending with the proximal cannula region of the hub structure and continuing through the full length of the cannula to emerge at the distal end and in turn blend smoothly with the device's internal transition passage

and then into the implantable catheter within the patient.

The presently claimed access device is suitable for both single-needle and standard hemodialysis, plasmapheresis, and fluid exchange therapy applications. For standard applications, which require two flow paths, the housing may be arranged and constructed to engage two needle hub assemblies, as described above, and include dual-lumen through passageways. When two needles and needle hubs are used, a bar may be provided that engages each needle hub, thereby locking both needles to each other to preclude inadvertent disconnection of only one needle, thereby enhancing patient safety. In another preferred embodiment the two needle hubs are prevented from moving laterally with respect to each other.

It is important to note that the primary object of this invention is to provide an implantable, subcutaneous access device suitable for applications requiring flow rates of 250 ml/min or greater, with low pressure drops along a streamlined flow path having substantially no stagnation pints or other flow discontinuities. Low pressure drops and substantial elimination of stagnation points are achieved by having maximum internal diameters of the flow path (and therefore thinnest cannula walls), smooth transition points where different elements of the device abut (*e.g.*, the cannula-transition element-catheter interface) and by having all changes in lumen diameter be of a gradual nature and having straight or nearly straight flow path without sharp curves or objects protruding into the flow path and no dead volume.

As indicat d earlier, because such large flow rates are desired with low resistance, it is necessary to have the largest needle outside diameter that patients will accept. Accordingly, rigidity of the puncture needle is desired. A rigid needle allows a greater inner lumen diameter per outer component diameter (*i.e.*, thinner walls) than does a flexible tube. This is important because it allows the needle to have as small a cross-sectional diameter as possible, thereby lessening the trauma on the patient's puncture site, yet still be capable of handling large flow rates. Flexible tubes require a much higher outer diameter to inner diameter aspect ratios to prevent kinking or tube collapse. Thus, to accommodate the bloodflows common during hemodialysis, a much larger outer diameter would be required if flexible materials were used. Also, a rigid needle allows a greater force to be transmitted to open the seal valve by overcoming the resistance provided by the spring. Thus, a greater contact sealing force can be employed, resulting in a more robust, reliable, and fault-tolerant valve seal.

Further, the lack of sharp angles or bends in the flow path is much less injurious to fragile hematocytes. Since the flow path from needle to catheter (or vice versa) is substantially straight, the fluid turbulence is minimized, the shear stresses are lessened, and flow directional changes are minimized resulting in less erythrocyte damage and a lowered tendency toward platelet activation.

Finally, a medically acceptable, water-based lubricant can be used on the needle exterior, as an enhanced lifespan has been observed when lubricant is used. Also,

a lubricated needle will penetrate the skin with less pain to the patient.

Other objects, features and advantages will be apparent from the following detailed description of preferred embodiments thereof taken in conjunction with the accompanying drawings in which:

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1A is a front axial view of an implantable access device of the present invention;

FIG. 1B is a superior plan view of an implantable access device of the present invention;

FIG. 1C is a side elevation of an implantable access device of the present invention;

FIG. 1D is a inferior plan view of an implantable access device of the present invention;

FIG. 1E is a rear axial view of an implantable access device of the present invention;

FIG. 2A is a cross-sectional view of the implantable access device of Fig. 1B taken through the line A-A' with a corresponding cannula/obturator assembly not inserted;

FIG. 2B shows the device of Fig. 2A with the corresponding cannula/obturator assembly inserted;

FIG. 3A is a cross-sectional view through the line B-B' of Fig. 2B;

FIG. 3B is the same view of FIG. 3A with the cannula twisted;
FIG. 3C is an alternate pictorial of the locking blades (distorted for illustration);
FIG. 3D is alternative blade design;
FIG. 4A is a cross sectional view of the valve guides and resilient seal with the needle cannula not inserted;
FIG. 4B is the same view of FIG. 4A with the needle cannula inserted;
FIG. 5 is a cross section view of the transition channel of an implantable access device of the present invention;
FIG. 6A is a side elevation of the obturator of the present invention;
FIG. 6B is a side elevation of the obturator of FIG. 6A rotated 90 degrees;
FIG. 7A is a cross sectional view of the cannula/obturator of the present invention;
FIG. 7B is a cross sectional view of FIG. 7A taken through line C-C';
FIG. 7C is a cross sectional view of FIG. 78A taken through the line D-D';
FIG. 8A is a side elevation view of an extracorporeal hub of the present invention being combined;
FIG. 8B is a side elevation of the extracorporeal cannula hub attached to one another; and
FIG. 8C is a cross sectional view of an extracorporeal cannula hub of the present invention.

BRIEF DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to the figures, wherein like reference numerals represent like parts throughout the several views, it is understood that the device is bilaterally

symmetrical through the various cross-sections taken and that corresponding halves of parts shown in cross-section represent cylindrical structures. It is further understood that the present invention contemplates a single implantable access device that accommodates a single needle/catheter fluid passage or a ganged plurality of such passages, or separate such devices, each accommodating either a single or ganged plurality of such passages.

Turning now to the drawings, FIGS. 1-8 show a dual-line channel embodiment of the implantable access device with corresponding cannula/obturator assemblies of the present invention. Access device 10, implantable just under the skin S of a patient, comprises a needle guidance element 12, a catheter locking element 16, and a protective cowling 14 accommodating these and related internal elements. For purposes of this discussion, it is understood that the embodiment contemplates dual passages; however, solely for simplicity of description, the elements will be referred to in the singular, as though only one passage were present.

Anatomical Mounting Plate

Referring back to FIG. 1A-1E, the mounting plate 60 has a plurality of eyelets 98 for suturing attachment to subcutaneous tissues. As discussed previously, the anatomical mounting plate attached to device 10 by means that allow the plate to pivot in relation to the device. This allows, in sequential hemodialysis sessions a day or two apart, the device 10, with ganged access to internal catheters to be pivoted to allow needle access

at different skin puncture sites while other such sites heal.

Protective cowling 14 has a lower surface 58 accommodating an anatomical mounting plate 60 by means of rivet 62 being disposed through lumen 64 of anatomical mounting plate and further through a mating opening in the lower surface of the protective cowling 14. The arrangement of mounting of the cowling 14 to the plate 60 allows the plate to pivot relative to the cowling 14. There is a shoulder 66 that acts to retain the pivot action by the plate striking the shoulder 66 to a zone of about 30° (*i.e.*, about 15° clockwise rotation and 15° counterclockwise rotation). Other ranges of pivoting can be used and other pivoting mounting arrangements suitable for use herein are known in the art.

There is a protective structure 16 surrounding the ends of a catheter. This structure 16 is attached to the cowling 14 and provides a means to retain the catheters to the device. The catheters may be attached to surrounding tissue to generally retain the catheters and , not shown, a shroud or other such strain relief elements may surround the catheters proximate the device, as is known in the art, to protect the ends of the catheters from undue stress or strain.

Focusing our attention on the individual components of device 10, FIGS. 1A-1E show an embodiment of needle guidance entrance 12 of the presently claimed invention. This entrance 12 has a inwardly sloped and concave first end bounded by conical ends 18 and 18' such that a rigid

implement, such as needle/obturator assembly 20, is guided to either entrance lumen 22 or lateral trough 24. The trough has a rounded cross section as shown in FIG. 1C, and the lowest surface of the trough is a straight connection between the two entrance apertures 18 and 18'. If the implement contacts trough 24, there is no structure or slope to impede the lateral movement of the implement to either aperture.

FIGS. 2A and 2B show an embodiment of lock assembly 26 in each channel of the dual lumen device. Lock assembly 26 comprises a silicone rubber plug 28 with a hollow elongated passage 30 therein accommodating the inserted needle with some clearance and one or more (preferably three, but variable from one to ten) radial locking blades 32. The blades 32 can be rectangular in longitudinal cross section or tapered as shown.

Referring to FIGS. 2B, 3A and 3B each blade 32 has an axial-direction-tapered outer edge 34 tapering towards the guidance element 12 entrance 22 and the guidance element 12 has a corresponding taper 36. FIG. 3A and 3B are cross sections through B-B'. Each blade also has an inner edge 38 which comprises one or more teeth preferably of shallow clearance angle ending in a point or small length contact with the cannula outer surface 40. Each blade has holes 42 allowing the plug to be continuous and retain the metal blades in relative positions to the rubber body and to each other. FIG. 3A shows the locking blades 32 hard against the cannula outer surface locking the cannula to the device. FIG. 3B which is a cross section as in FIG. 3A except showing the effect of twisting the cannula so that the blades are

not aligned radially to the cannula. The locking blades 32 pivot about their outer edges and the inner edges 38 and teeth move away 44 from the cannula and provide little retaining force on the cannula. Twisting the cannula while axially withdrawing the cannula allows the cannula to be extracted with little force. To accommodate this withdrawing, the cross section of the blades may be tapered from the outer edges 34 to the inner edges 38. After the cannula is withdrawn, the plug and blades return to the original position, shown in FIG. 3A.

Other forms of the blades are shown in FIGS. 3C and 3D. In FIG. 3C, the blades 32 are cross-section tapered (distorted for illustration) to establish corners C1, C2 as pivot points for accommodating tilting of blades from radial to non-radial alignment as cannula 40 is twisted. FIG. 3D shows a form of blade that has a limited length outer edge 34 compared to blade length as a whole. The blade can be rectangular in cross-section or tapered as in FIG. 3C. It is contained in the plug without a need for holes, but one such hole 42 can be provided optionally

FIGS. 1A-1E, 2A and 2B show an embodiment of a protective cowling 14 that defines a space 46 capable of accommodating needle guidance means 48, needle alignment means 50, a cannula seal 92, flexible valve seal 52, elastomer 54, and transition channel 56. the needle assembly penetrates the locking mechanism 26 and continues through the ring seal 92. This ring seal 92 prevents leakage as the cannula is removed after use. The needle assembly continues to penetrate to the rigid

guide elements 50 which force open the slit in the seal 52, as described later. An elastomer 54 surrounds the seal 52, both 52 and 54 are made of elastomeric materials . However, the valve seal 52 is more supple with a lower durometer rating than that of elastomer 54. The more supple material accommodates particles or other small debris that may be attached to the needle assembly and still provides a good seal.

FIG. 4A shows the obturator tip just before entering the rigid guides 50. The guides are retained by a retaining disk 49 and the seal 52. The device also comprises the above mentioned valve structure, seated between a retaining disk 49, in turn, as shown in FIG. 2A, held at an annular shoulder 90 of needle guidance element 12 and supporting needle alignment ring 92, and catheter connector retaining ring 68, held at annular shoulder 94 of protective cowling 14 (or radial inserts instead of a ring). The valve is maintained in an elongated position, such that it does not dislodge during needle insertion or withdrawal, by retaining element 96 and the cowling. Referring back to FIG. 4A, the valve has opposing guide elements 50 with a surface hardened to a point higher that of the steel used in the obturator. These elements may be made of ceramic or coated with a hard material, like titanium nitride. The valve seal 52 is formed with sealing portion with a slit 53 that is axially aligned with the obturator. The guide elements have extensions 57 that seat in apertures in the sealing portion. This intimate contact of the guide elements and the seal compels the slit to follow the ends 57 of guide elements. When these ends 57 open the slit 53 opens as shown in FIG. 4B. There is a retaining ring 51 encircling

the guide elements distal from the slit. This ring 51 acts as a pivot point when the guide elements open. The hardened surfaces of the guide elements are tapered 55 toward the slit and guide the needle assembly to the slit. Referring to FIG. 4B, the outer diameter of the needle assembly or the obturator contacts the guide assembly and opens the guide elements before the point 63 of the needle assembly reaches the slit. As illustrated, the guide elements pivot about the retaining ring. The elastomer material 54 substantially surrounds the seal 52. As mentioned above, the elastomer 54 and the seal 52 are constructed with a differnet durometer levels that separate the sealing attrribute fromt the forcing means. As the guides open, both the elastomer 52 and seal 54 resist the opening and, as the needle assembly penetrates completely through the slit 53, the elastomer and the seal conform around the needle assembly surface to form a seal thereto. The elastomers are providing an inward radial force urging the slit closed. The obturator may be removed and the elastomer 54 is forcing the seal 52 to conform to the outer cylindrical surface of the cannula to form a seal thereto. When the cannula is removed the slit closes by the elastomeric action of the 54 and 52 materials.

FIG. 5 shows an embodiment of one of the matching pair of connecting transition channels 56 shown in FIG. 2A and 2B. These elements provide a flanged end 68 that is retained in the cowling. The fully inserted cannula matches and mates with the channeled surface 70. The internal diameter 72 matches that of the cannula and the transition channel provides fairing for a transition from the cannula internal diameter to the internal diameter of

the catheter. This construction minimizes any flow discontinuities. The 74 end of the transition element has flared extensions 76 and 76'. The catheter slips over these extensions and is retained thereby and by the element 16 (FIG. 2A). FIG. 5 needle/cannula seat/catheter attachment transition channel 56 has a barrel segment 78

Referring back to FIG. 2A, The retaining flange 68 is disposed within space 46 of protective cowling 14, such that it is held at annular shoulder 80 of protective cowling 14, and further, such that barrel segment 78 is disposed within lumen 82 of protective cowling 14. Catheter connector retaining flange 68 itself defines an annular shoulder capable of accommodating valve seating means 54. The transition channel 56 further defines an axial lumen 84 having disposed at some point along its length needle stop 86, shown here as a conical narrowing of lumen 84, although other designs are contemplated. It is imperative to the purposes of this invention, however, that all transitions in lumen diameter be sufficiently gradual as to inhibit damaging delicate blood cells.

Flow in the Access Device(s)

Focusing again on FIGS. 2A and 2B, it is seen that the internal passage can be very short, that a generally straight flow path is established and that the inner diameter of the cannula can be larger than is conventional. These factors reduce the flow resistance and allow the device to accommodate high fluid flow rates with low shear (*i.e.*, lower than state of the art

shear rates, generally, and short residence time at highest shear rate zones) and to limit other deleterious effects as to the fluid passing through.

The needle assembly (discussed in more detail in connection with FIGS. 6A, 6B, 7A, and 7B below) has an interior obturator nail and surrounding needle cannula sheath that can be of very thin wall construction. Thus for a standard cannula outer diameter of .072 in. an inner diameter of .0673 in. (compared to a standard of .064 in.) can be provided because of obturator reinforcement. That .0033 in. difference in inner diameter affords, approximately, a greater than 20% decrease in flow resistance. The obturator also prevents a coring or cookie cutter effect that can arise from using a hollow needle for subcutaneous accessing.

Needle/Obturator Assembly

FIGS. 6A, 6B, and 6C shows an axial section of the piercing end of the needle assembly with the needle cannula 40 having a wall end 100 that is beveled to blend with the obturator to lessen the resistance to penetrating tissue and the inventive device. The cannula end 100 also seats firmly on a corresponding conical stop 86 within axial lumen 84 portion of transition channel 56 (FIG. 5). Obturator tip 102 has a distal end with multiple facets (preferably three) as shown in FIGS. 6A and 6B. These facets may be concave to provide sharper cutting edges. The part of the point 104 that blend the cutting edges with the outer surface of the obturator is dulled by providing a greater number of facets providing a smooth transition from point and cutting edges to cylindrical form.

Obturator cutting for skin penetration is done along meeting lines of distal end facets, rather than solely or primarily at the distal point. This avoids pain to the patient, since the cut is over a short length and does not tear skin over a significant length. However, when the obturator point enters entrance lumen 22 of device 10 and passes therethrough , it does not cut, score or otherwise mar the internal wall of the lumen or interiors of the locking and sealing components of device 10 that extend from the lumen.

The dulled section 104 does not score the internal passage of the device. Once the needle assembly is fully inserted and its cannula shell is locked in and sealed, obturator 106 can be withdrawn to leave a smooth flow path beginning in passageway 108 of hub structure 110 (FIG. 8C) and continuing therein to a smooth blending with passageway 112 of hub structure and continuing through the full length of the cannula, the length of the transition channel and then into the implantable catheter within the patient.

FIG. 7A shows the needle assembly with a chordal channel 77 cut into the obturator. The cross section of FIG. 7B shows the channel, as compared to FIG. 7C showing the uncut obturator. The passageway allows air to escape while inserting the needle assembly.

Extracorporeal Needle Hub

FIG. 8C shows an extracorporeal hub structure 110 associated with each access device 10. The hub structure comprises hub body 114 defining a Y-shaped arrangement of three internal passageways 108, 116, and 112 provided, respectively, for connection to a blood

line 118 from a dialysis machine, accommodation of obturator 106 , such that a long extension of the obturator or an extension rod or linkage connected thereto can be accommodated (in either case with an operating handle that allows axial pushing/pulling of obturator, and the needle/obturator assembly 20). It is contemplated that hub structure 110 comprise two mating halves of plastic, as shown, or metal or ceramic meeting at a surface 120 and as assembled by adhesives, solvent bonding, or other means or cast as a single piece. Needle cannula 40 terminates within collar 122 and is bonded thereto. Collar 122 is in turn securely attached to operating handle 114 such that collar 122 abuts retaining lip 124 of operating handle 114. Thus, rotating the hub structure as a whole rotates the needle cannula 40 for unlocking the cannula within device 10, as described above. Alternatively an inserted sleeve with dial access can provide a similar control. Passageway 116 flares outward at its proximal end to form control entry 126 for insertion of needle/obturator assembly 20. Flexible insert 128 is disposed within passageway 108 so that it defines a gradual bend in passageway 108 of sufficient arc to align passageway 108 with passageway 112. Insert 128 has a sealed plug portion 130 closing off passageway 116 where it communicates with passageway 108. Sealed plug 130 is pierced by obturator on initial insertion of needle/obturator assembly, allowing communication of passageway 116 with passageway 112.

Passageways 108, 116, 112 have smooth internal flow path radii in the flow path section. Generally, passageways 108, 116, and 112 (as well as control entry 126, needle/obturator assembly, and entrance lumens 22

of device 10) are of round form, preferably, but can be square or triangular or oval form or other shape.

When obturator is removed from hub after subcutaneous insertion of needle/obturator assembly into device 10, but prior to the start of the treatment session, sealed plug portion 130 self-seals the communication, thereby preventing fluid flow through passageway 116 during treatment. To further ensure that fluid is not lost through passageway 116 during treatment, a cap 132 can be secured to operating handle 114 at control entry 126 by means of lip 134, which may optionally take the form of a screw thread or other shape capable of cooperating with the internal shape of cap to ensure a secure fit of cap to operating handle 114.

Operating handle 114 is provided with locking means having a joining surface that forms alternating recesses 136 and protrusions 138 such that, when two hub structures are used with a device 10 having at least two passageways 22, the respective joining surfaces of the hub structures 110 may be matingly fitted together, as shown in FIG. 8A, to prevent rotational movement of either hub structure or their related needle cannulæ when the cannulæ are inserted into the device 10. Moving of either hub structure away from the other will allow rotational movement of either hub structure 110, as necessary for withdrawal of needle canulæ. FIG. 8B show a wrapping 140 around the two structures will retain each to the other in a locking fashion.

Variants

There can be non-annular forms of the locking device. For example, the parts shown as annular pieces or arrays in FIGS. 2-3 can be part-annular. The locking

blad s can be of various other forms, *e.g.*, blocks, balls, rollers. Springs or coil or leaf or other types can be used to assist locking or unlocking actions. The locking action can involve inscribing a cannula outer surface, holding it by friction or geometric blocking of a locking element with a rib or other protrusion on such surface. The plug seal and/or its closing bias spring can be of various forms and of different materials as are known in the art.

It will now be apparent to those skilled in the art that other embodiments, improvements, details, and uses can be made consistent with the letter and spirit of the foregoing disclosure and within the scope of this patent, which is limited only by the following claims, construed in accordance with the patent law, including the doctrine of equivalents.

What is claimed is:

1. A subcutaneous implantable access device for transferring fluid into and/or out of a human or animal body, said access device arranged for receiving a needle assembly passing through the skin and an implanted catheter, where said fluid passes from said needle assembly to said catheter, the improvement comprising a flow path streamlined with substantially no flow discontinuities.

2. The device of claim 1 wherein said no flow discontinuities comprises no eddy flow currents, no stagnant flow volumes, no sharp edges, no immediate changes in flow direction, no severe changes in flow cross section areas, and no objects protruding into the flow stream.

3. The device of Claim 1, wherein said needle assembly includes a cannula, and further comprising:
an internal transition passageway, said transition passageway having a first end matingly joined to a proximal end of said catheter, and said transition passageway having a second end matingly joined to the proximal end of the cannula, and where said transition passageway has an internal diameter at said first end substantially the equal to the internal diameter of the catheter, and an internal diameter at said second end substantially equal to the internal diameter of said cannula, and where said internal passageway provides a smooth transition from said first to said second end with no flow discontinuities.

4. The device in claim 3 wherein said internal passageway provides a circumferential shoulder at said second end that abuts the tubular was of the inserted end of the cannula, and where said conduit provides a tubular first end with walls that substantially meld with the internal wall of the catheter, and where the flow path through the internal passageway is short and substantially straight.

5. The device of claim 3 wherein the catheter proximate the device is attached to the surrounding tissue, but where the device is movable beneath the skin.

6. The device of claim 1 further comprising: valve means defining an opened and a closed position, said valve means including a sealing portion with a closable passageway that when closed resists the passage of fluid when the needle assembly is not inserted into the device, and that allows fluid to flow when opened when the needle assembly is inserted therein.

7. The device of claim 6 wherein said sealing portion is a solid resilient blank or plug with a closable through passageway formed by slitting said plug, and where said slit forms the path through which the needle assembly is inserted.

8. The device of claim 6 further comprising spring means for urging said valve means into the closed position.

9. The device of claim 8 further comprising:

a flexible seal,

means to open said valve, said means to open includes the needle assembly pushing through said valve means, and where said spring means comprises an elastomer wrapped around the sealing portion..

10. The device of claim 6 wherein said valve means comprises:

guide means with a rigid surface for accepting and guiding said needle assembly into alignment with said closable passageway, said guide means constructed to open when the needle assembly penetrates said guide means, said guide means in intimate contact with said sealing portion and constructed and arranged such that said guide means opens said closable passageway such that the point of the needle assembly enters an opened closable passageway.

11. The device of claim 10 wherein said guide means comprises:

two opposing elements, and

means for forcing said elements together, where each element is tapered such that when together forms a guide path ending suitable for receiving the tip of the needle assembly.

12. The device of claim 11 wherein said guide path is tapered, and where means for forcing is derived from said spring means for urging.

13. The device of claim 10 wherein said needle assembly comprises:

an obturator that contacts and forces open said guide means,

said guide means rigid surface construct d hav a hardness greater than the needle assembly hardness and arranged to receive the point of said needle assembly without any damage to said rigid surface.

14. The device as claimed in claim 6 further wherein said needle assembly comprises:
a cannula having a wall thickness of about 0,07 to about 0.15 mm and a rigidity sufficient to maintain said valve in said open position, and an obturator matingly inserted in said cannula, said obturator with a pointed end constructed for opening said valve means.

15 The device as claimed in any of claims 1, 6 an 10 wherein said access device is arranged and constructed for receiving at least two said needle assemblies.

16. A needle assembly for subcutaneous access for transfer of fluid into and/or out of a human or animal body comprising thin walled cannula and an internal obturator rod matingly inserted through said cannula and said obturator having a solid cylindrical body with a tip with a pointed end and where said tip and said body blends smoothly into each other, and where said pointed end is constructed to cut through the skin without substantial stretching and without tearing and without damage to an access device.

17. The needle assembly of claim 16 wherein said obturator point end comprises first facets such that the tip of the needle is formed of intersecting edges of said facets such that said intersecting edges cut through said skin without tearing, and where said intersection edges are dulled as said edges approach the outer cylindrical surface of the obturator..

18. The needle assembly of claim 17 wherein said duller edges comprises second facets constructed at the transition from the tip to the outer cylindrical surface of the obturator said second facets being smaller and more numerous than said first facets.

19. The needle assembly of claim 16 further comprising an axial cut away portion of said obturator that provides an air escape passage within the cannula interior.

20. In an access device for subcutaneous access for transfer of fluid into and/or out of a human or animal body and defining at least one internal passage, where each said internal passage provides access at one end by a cannula passing through the skin and at the other end by a catheter, the improvement therein comprising:
(a) locking structure within the device adjacent the internal passage and any cannula therein and restrained within the device,
(b) means defining a structure surrounding the locking structure and having an internal surface adjacent to the locking structure, and constructed and arranged to increase the locking force that in turn restrains cannula axial removal,

21. The access device of claim 20 further comprising:
(c) means defining at least one essentially rigid blade spanning the gap between the surface of a cannula inserted in the passage and said internal surface, and
(d) the said internal surface being tapered toward the device entrance so that the beginning of inadvertent cannula withdrawal motion produces an increase in

locking force against the blade that in turn restrains cannula axial movement,
the foregoing structure being constructed and arranged so that twisting the cannula pushes each blade from its locking alignment to an unlocking alignment to allow easy cannula withdrawal.

22. Device as defined claim 21 wherein two or more blades are provided.

23. Device as defined in claim 22 wherein the blades also have an outer edge proximate said internal surface of said shell, wherein said outer edge tapers down towards the cannula entrance to said device, said taper, corresponding to the taper of said shell internal surface.

24. Device as defined in claim 20 and further comprising a flexible sealing portion that is held out of the fluid passage when the cannula is inserted and is urged into the passage to block it when the cannula is withdrawn.

25. The device of claim 24 wherein elastic element means is provided to urge said seal to block said passage.

26. A subcutaneous access device for transferring fluid into and/or out of a human or animal body via a needle assembly piercing the skin comprising:
a mount for said access device, said mount attached to the surrounding tissue,
a movable connection between said mount and said access device, said connection arranged and constructed to allow the access device to move relative to the skin surface so that virgin skin is provided for piercing.

27. The mount of claim 26 wherein said movable connection is a pivot

28. A dual subcutaneous access device for transferring fluid into and/or out of a human or animal body with an entrance section arranged for accepting and guiding two needle assemblies passing through the skin, said entrance section comprising:

a generally sloped surface adapted for receiving said needle assemblies, where said sloped surface defines a trough surface, said trough surface described by dividing a truncated funnel along an axial plane and stretching the two parts away from each other and connecting the two parts along the stretch lines, defining a trough floor where the funnel truncated portion is stretched, and two apertures, each suitable for receiving a needle, disposed on said trough floor.

29. In two or more percutaneous needle structures, aligned parallel to each other after insertion through the skin of a patient, and improvement comprising: means to lock each needle structure to each other to prevent relative motion of one such needle structure to the other.

30. The needle structures of claim 29 wherein the lock comprises a bar removably attached to each said structure.

31. A percutaneous needle hub structure comprising:

a structure suitable for operating external to the skin having a through barrel chamber

a cannula with a first axis axially aligned with the barrel chamber and attached to a first end of the through

barrel chamber,
an entry port at the second end of the barrel chamber, said entry port arranged to accept an obturator and direct the obturator through said barrel chamber and through the cannula to form a point suitable for piercing the skin and a blood or other body vessel, such that when said obturator is removed the cannula forms a linkage from the barrel chamber to a blood vessel, sealing means formed in the second end of the barrel chamber, said sealing means penetratable by the obturator and forming a seal around said obturator, and further sealing the second end of the barrel chamber from the cannula when the obturator is removed,
a passage defining an axis, said axis substantially forming a shallow angle with the barrel chamber axis, said passage communicating with the barrel chamber in a streamlined fashion and where the internal surfaces of the barrel chamber and the passage are smooth with a gradual, rounded smooth flow bend along the intersection of the barrel and the passage.

32. The device of claim 31 further comprising: means for preventing motion constructed as an external part of said hub structure to allow mating with the corresponding structure of a second needle hub, where said means for preventing motion is defined when two such corresponding structures for preventing motion are in intimate contact.

33. The device of claim 29 wherein said means for preventing motion are a bar connecting the two hub structures, said bar attached to each hub structure and preventing relative motion therebetween.

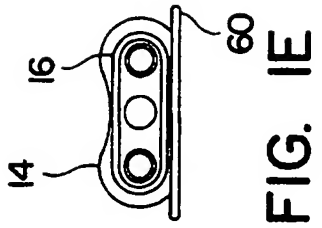

FIG. 1E

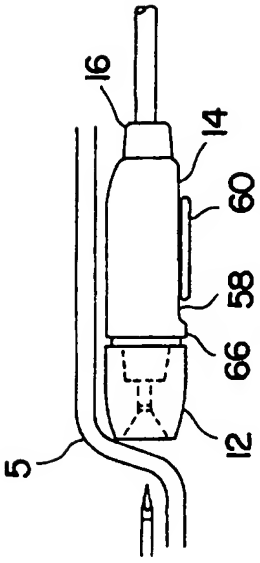

FIG. 1C

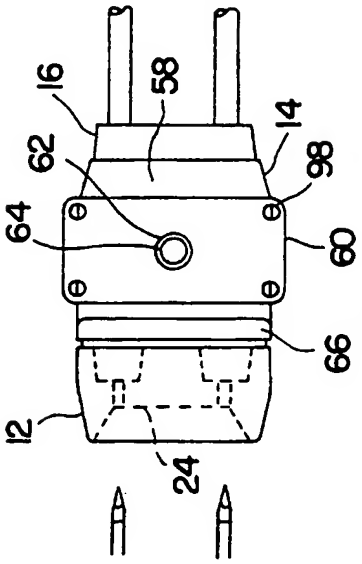

FIG. 1D

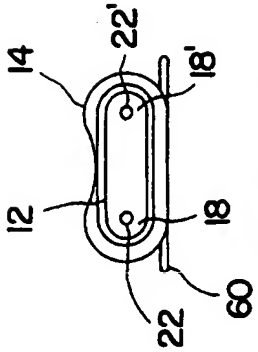

FIG. 1A

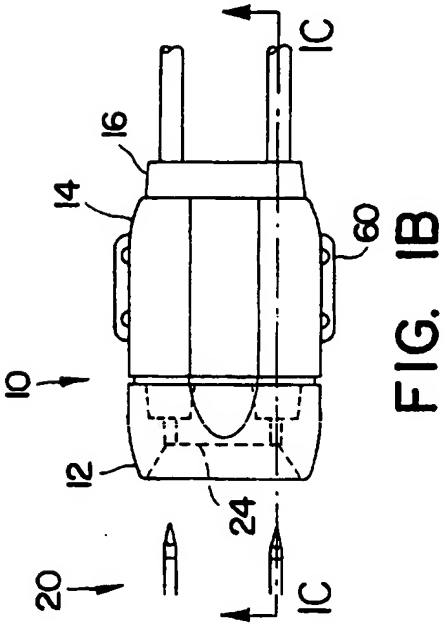

FIG. 1B

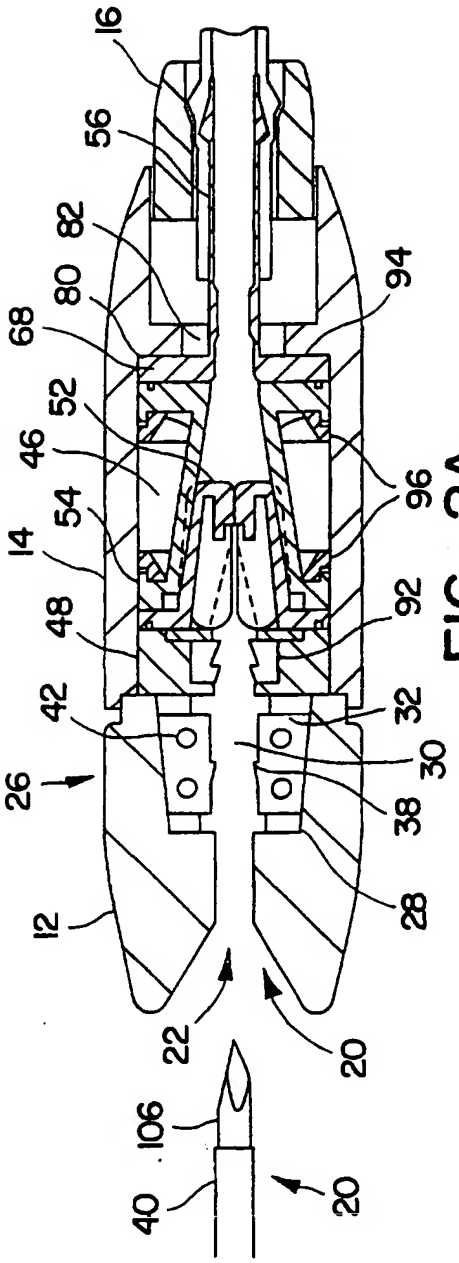
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FIG. 2A

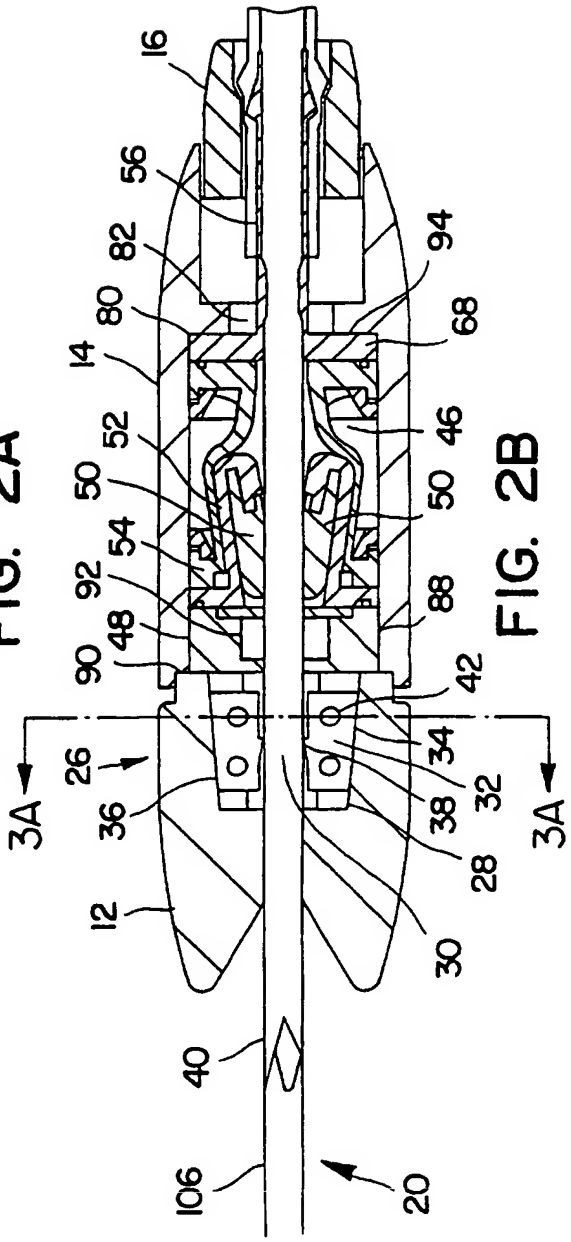
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FIG. 2B

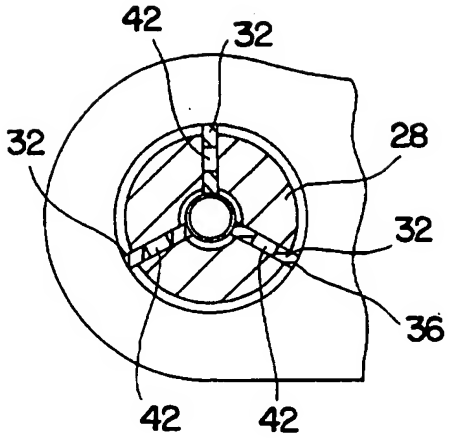

FIG. 3A

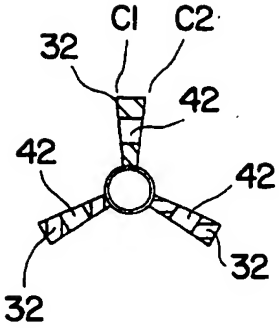

FIG. 3C

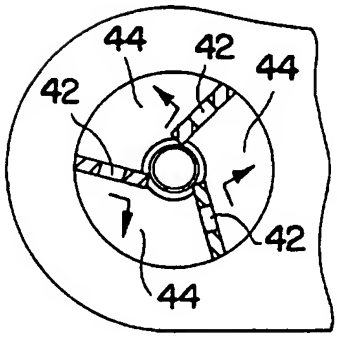

FIG. 3B

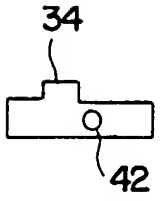

FIG. 3D

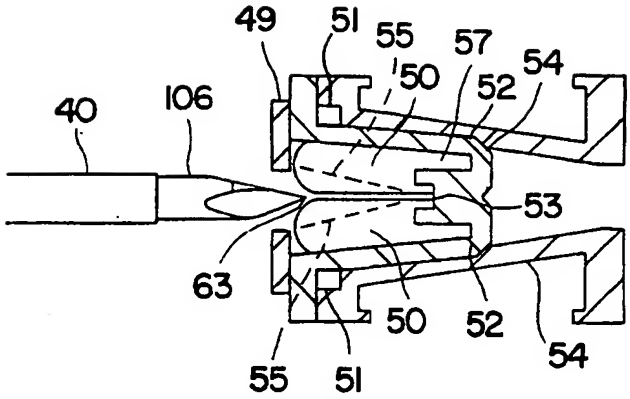

FIG. 4A

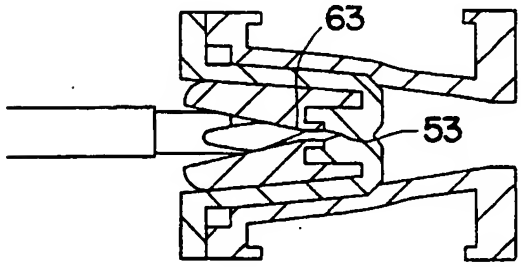

FIG. 4B

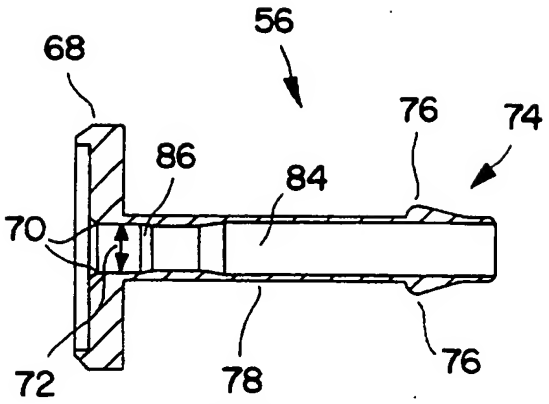

FIG. 5

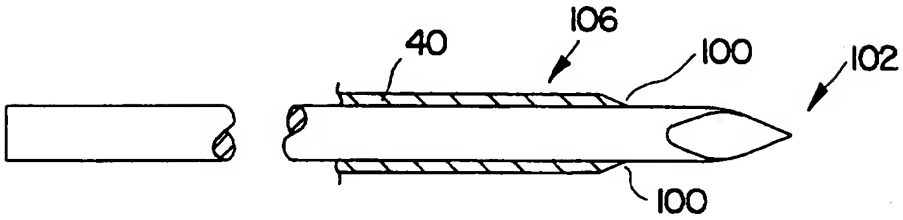

FIG. 6A

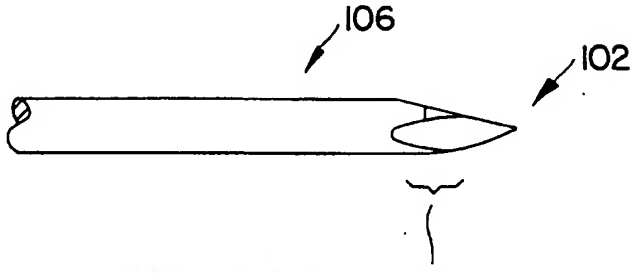

FIG. 6B

FIG. 6C

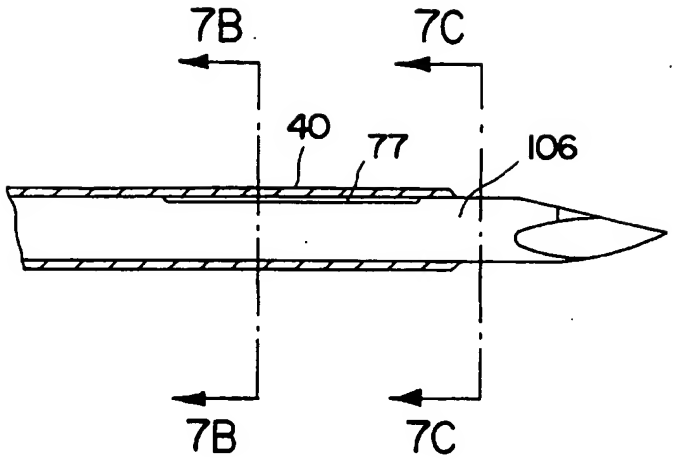

FIG. 7A

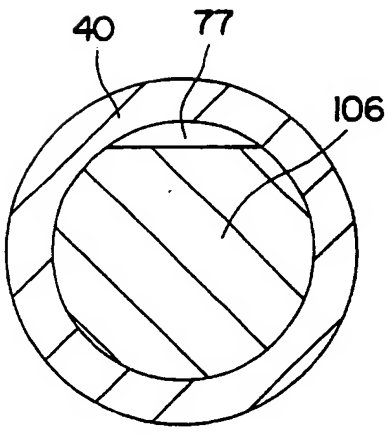

FIG. 7B

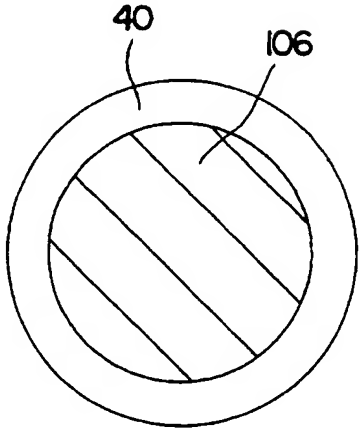

FIG. 7C

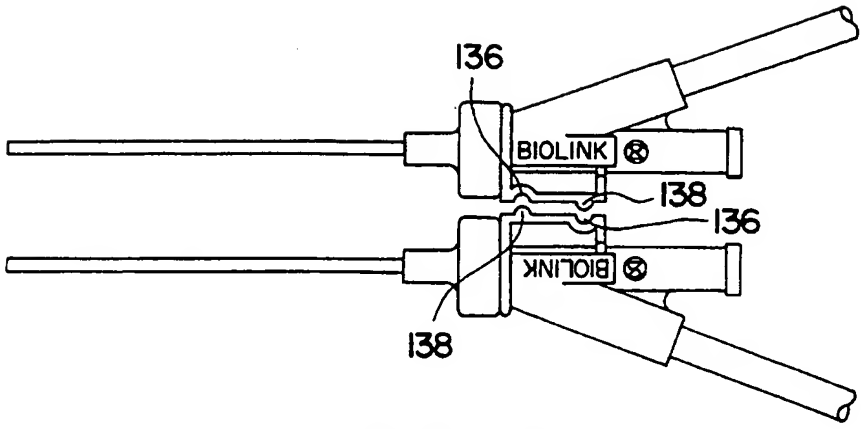

FIG. 8A

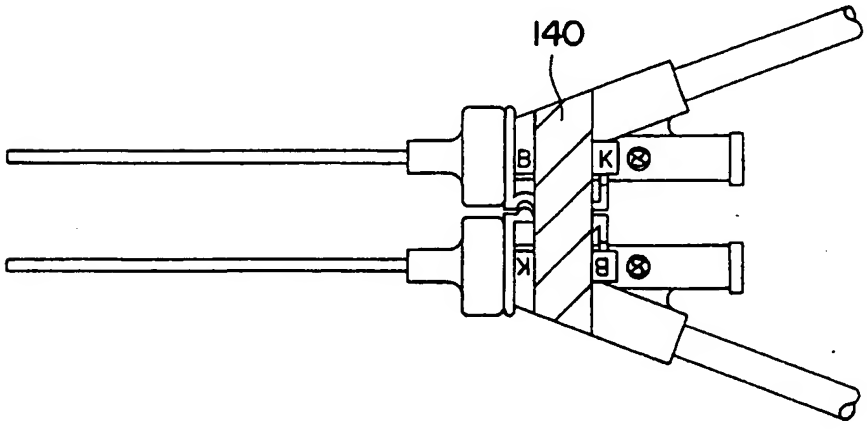

FIG. 8B

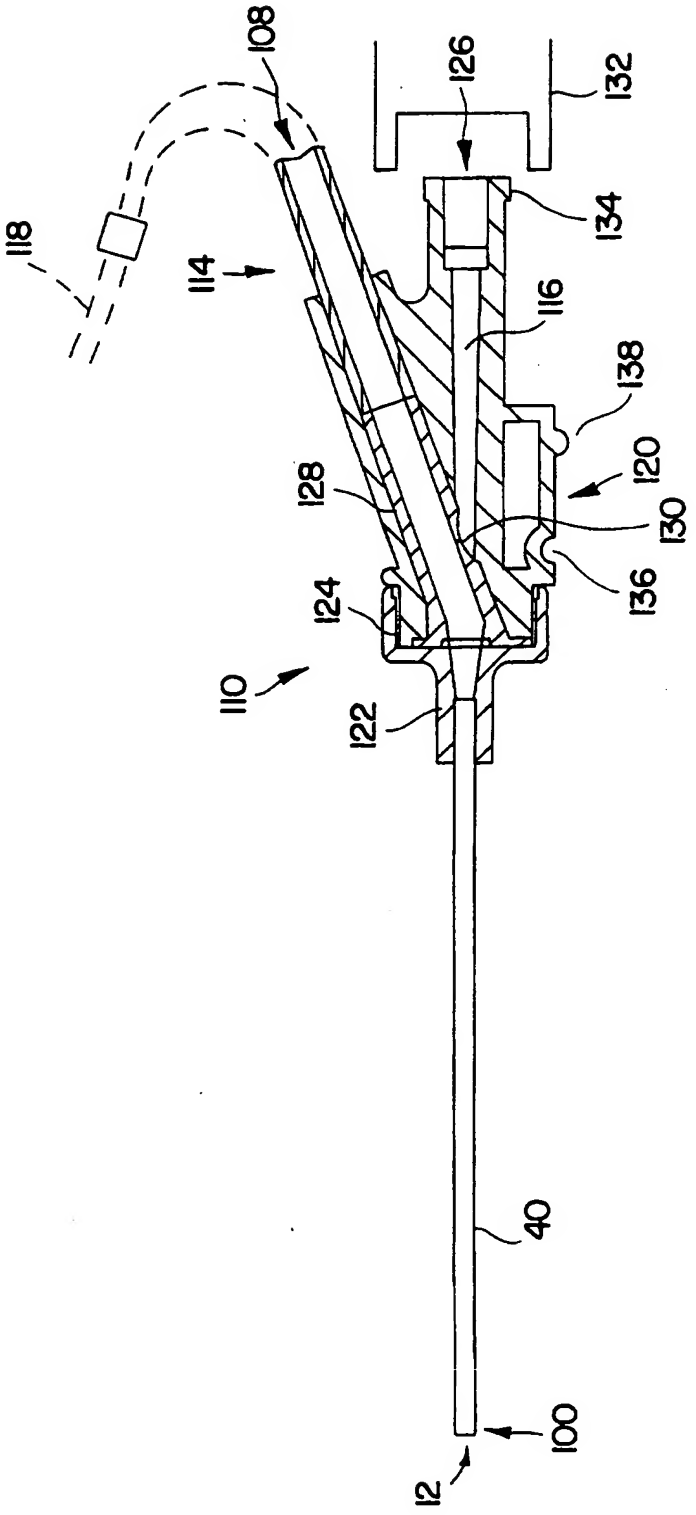
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FIG. 8C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/17534

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 5/00, 32, 11/00
US CL :604/93, 175

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/912, DIG. 26; 604/93, 174, 175, 283, 891.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS
search terms: subcutaneous, implantable, catheter, lock

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---, P A	US 5,556,381 A (ENSMINGER et al) 17 September 1996, see entire document.	1-19, 26-33 --- 20-25
A	US 4,704,103 A (STOBER et al) 03 November 1987, see entire document.	20-25
A	US 5,178,612 A (FENTON, JR.) 12 January 1993, see entire document.	20-25

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 30 JANUARY 1997	Date of mailing of the international search report 19 FEB 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer Marc L Smith for ROBERT V. RACUNAS Telephone No. (703) 308-3589

Form PCT/ISA/210 (second sheet)(July 1992)*